

REMARKS

Claims 1-3, 5-11 and 13-15 were pending when the present Office Action was mailed on January 21, 2009. In this response, claim 9 has been amended, and claims 5, 6, 8, 11, 13 and 14 have been canceled without prejudice to pursuing the canceled subject matter in a related application. A Notice of Appeal is filed concurrently with this paper. This appeal is properly filed because the claims have been rejected many times in several office actions over the last ten years, and in particular the last three Non-Final Office Action dated 22 August 2007, 17 March 2008 and 21 January 2009 have maintained substantially the same substantive rejections of the pending claims. Therefore, claims 1-3, 7, 9, 10 and 15 are pending in this application for appeal to the Board of Patent Appeals and Interferences.

This paper is being filed to present the amendment to claim 9 for appeal, cancel claims 5, 6, 13 and 14 without prejudice, and to address some of the Examiner's statements regarding the Declaration of Dr. Michael D. Laufer, M.D. Under 37 C.F.R. § 1.132 (the "Dr. Laufer Declaration") and the Personal Interview on June 25, 2008, attended by Examiner Shay, Dr. Michael D. Laufer, Ms. Nena Bains and the undersigned representative (the "June 2008 Interview"). The applicant does not concede Examiner Shay's statements and conclusions regarding the Dr. Laufer Declaration, or his statements regarding the June 2008 Interview set forth on pages 2-9 of the Office Action dated January 21, 2009 ("Current Office Action"). Although the applicant will substantively address Examiner Shay's summary, statements and conclusions regarding the Dr. Laufer Declaration in an appeal brief that will be filed in the course of the appeal of the present application, the applicant is compelled to respond in this paper to Examiner Shay's incorrect characterization of the statements made during the June 2008 Interview.

Examiner Shay indicated that the Interview Summary he provided regarding the June 2008 Interview was based on the oral presentation of the affidavit. Examiner Shay was given a draft of the Dr. Laufer Declaration during the June 2008 Interview, and the

discussion during the June 2008 Interview addressed Examiner Shay's incorrect characterizations of the applied references and faulty rationale and conclusions that formed the bases for the Section 103 rejection set forth in the Office Action dated March 17, 2008. Dr. Laufer's presentation during the June 2008 Interview, which is set forth accurately in the Dr. Laufer Declaration, provided facts that directly refute the Examiner's characterizations and conclusions regarding the applied references. For example, claim 1 includes "irradiating a length of the airway with a light source having a wavelength of about 240 nm to about 280 nm and an intensity which causes a change in the airway such that a thickness of the airway smooth muscle decreases and bronchoconstriction of the airway is reduced." In rejecting claim 1, Examiner Shay states on pages 11-12 of the Current Office Action:

It would have been obvious to the artisan of ordinary skill [to] use the method of Clarke (US '033) for treating asthma, since bronchial smooth muscle cells and vascular smooth muscle cells are equivalent, as taught by Waksman et al., and both asthma and restenosis involve hypertrophy of smooth muscle cells, as taught by James et al. and Regunathan et al., and to move the device while irradiating, since this would allow the treatment longer lesions, thus producing a method such as claimed.

In contrast to the Examiner's assertions, the Dr. Laufer Declaration provides facts which establish (a) the meaning of the applied references to a person of ordinary skill in the art at the time of the invention, and (b) the prevailing view at the time of the invention was that damaging airway walls, such as by debulking of smooth muscle tissue, for purposes of treating asthma may have negative effects because airway smooth muscle tissue was thought to be important for lung function. These facts directly refute Examiner Shay's characterizations of the applied references and hypotheses for the previous and current rejections of the claimed method for treating asthma. As such, because the Dr. Laufer Declaration refutes Examiner Shay's bases for the previous and current rejections of the claimed invention, the Dr. Laufer Declaration is in fact drawn to the patentability of the claimed invention.

Examiner Shay also infers that he was not informed of Dr. Laufer's interest in the pending application. The Examiner is simply incorrect. Ms. Bains prepared notes regarding Dr. Laufer's interest in Asthmatx Inc. before the June 2008 Interview, and Ms. Bains referred to those notes while making introductory statements to Examiner Shay which forthrightly informed Examiner Shay that Dr. Laufer (a) founded Broncus Technologies, Inc., which became Asthmatx, Inc., (b) is a Board Member of and paid consultant for Asthmatx, Inc., and (c) holds option and stock interests in Asthmatx, Inc., as set forth in Paragraph 4 of the Dr. Laufer Declaration. As such, even though Examiner Shay apparently does not recall Ms. Bains' introductory statements, she fully informed him of Dr. Laufer's interest in the application at the start of the June 2008 Interview.

Examiner Shay further asserts that there was an inference or even express statement during the June 2008 Interview "that the denial by the FDA was for the claimed method." (Current Office Action, page 5.) The Examiner appears to infer that there was some nefarious intent during the June 2008 Interview, but the Examiner is again incorrect. Paragraph 9 of the draft Dr. Laufer Declaration shown to Examiner Shay during the June 2008 Interview read as follows:

In 1998, the United States Food and Drug Administration also held the prevailing view of the time that airway smooth muscle was important for normal lung function. This was one reason why the United States Food and Drug Administration did not grant Asthmatx, Inc, approval to treat asthma in a human patient by debulking airway smooth muscle tissue until 2005.

The only change between this language and Paragraph 9 in the Dr. Laufer Declaration filed in the USPTO is an additional quote from the United States Food and Drug Administration ("FDA") supporting Dr. Laufer's factual statement. As discussed during the June 2008 Interview, the denial by the FDA is factual evidence that the prevailing view of a person of ordinary skill in the art at the time of the invention was that debulking of smooth muscle tissue for purposes of treating asthma may have negative effects on asthma patients because airway smooth muscle tissue was thought to be important for lung function. The statements regarding the FDA were directed to the FDA's initial

assessment that the mechanism of action and the results of the claimed method, namely debulking of airway smooth muscle tissue so as to reduce airway contraction to treat asthma, were sufficiently controversial that the FDA refused to approve the mechanism of debulking smooth muscle for treating asthma patients. Thus, the discussion during the June 2008 Interview was not misleading in anyway.

In the Current Office Action, claims 1-3, 5-11 and 13-15 were rejected. More specifically, the status of the application in light of the Office Action is as follows:

- (A) Claim 1-3, 5-11 and 13-15 were rejected under 35 U.S.C. § 112, first paragraph;
- (B) Claim 1-3, 5-11 and 13-15 were rejected under 35 U.S.C. § 112, second paragraph;
- (C) Claims 1-3, 5-11 and 13-15 were rejected under 35 U.S.C. § 102(b) over Ivanyuta et al., *Effect of Low-Power Laser Irradiation of Bronchial Mucosa on the State of Systemic and Local Immunity in Patients with Chronic Bronchitis* ("Ivanyuta");
- (D) Claims 1-3, 5-11 and 13-15 were rejected under 35 U.S.C. § 103(a) over the combination of James et al., *The Mechanics of Airway Narrowing Asthma* ("James"), U.S. Patent No. 5,053,033 to Clarke ("Clarke"), U.S. Patent No. 5,574,059 to Regunathan et al. ("Regunathan"), and International Publication No. WO97/37715 to Waksman et al. ("Waksman"); and
- (E) Various combinations of the pending claims were rejected under the doctrine of obviousness-type double patenting over one or more claims of several copending applications and issued patents as set forth below in Section E.

A. Response to § 112, first paragraph Rejection

Claim 1-3, 5-11 and 13-15 were rejected under 35 U.S.C. § 112, first paragraph, on the grounds that the disclosure does not teach how radiation with a wavelength of about 240 nm to about 280 nm could be effectively applied to mucus cells that lie below the smooth muscle cells. Claims 1, 2, 7 and 9 are not limited to changing mucus gland cells, and thus this rejection is incorrect on its face with respect to at least claims 1, 2, 7 and 9. Only claims 3, 10 and 15 include changing airway mucus gland cells.

The rejection of claims 3, 10 and 15 under Section 112 is further incorrect because (a) the Examiner mischaracterizes James, and (b) the combination of James and U.S. Patent No. 4,784,135 ("Blum") cited by the Examiner establish that a person of ordinary skill in the art could make and use the claimed methods without undue experimentation. The Examiner asserts that James teaches the submucosa and epithelium cells are about "65 microns thick." The Examiner is wrong on this statement. The text of James cited by the Examiner does not state that the submucosa and epithelium layers are 65 μm thick, but rather James teaches that the wall "area" of 2 mm airways is 65 μm^2 (\pm 49 μm^2). The Examiner accordingly incorrectly characterizes the area (μm^2) of a cross-section of the airway as the thickness (μm) of the cross-section. This is important because mathematically the single-dimensional wall thickness must be less than the two-dimensional wall area, and thus the wall thickness disclosed in James must be less than the 65 μm incorrectly asserted by the Examiner. With respect to Blum, the Examiner states that Blum teaches "ultraviolet light is strongly absorbed and extinguished within a few microns." However, the portion of Blum cited by the Examiner teaches that ultraviolet radiation at 193 nm produces a groove approximately 150 μm deep as opposed to "only a few microns." The 193 nm UV radiation taught by Blum can accordingly penetrate tissue to a depth of 150 μm - more than 200% deeper than the wall thickness the Examiner purports is taught by James. This Section 112 rejection should accordingly be withdrawn because the Examiner's rationale is not supported by the references themselves.

Moreover, a person skilled in the art could carry out the claimed invention using radiation having a wavelength of 240 nm - 280 nm without undue experimentation based on the teachings of James and Blum. The claimed UV radiation range of 240 nm to 280 nm will penetrate to a depth of more than 150 μm at similar pulse/power parameters because of its longer wavelength. As a result, the claimed 240 nm - 280 nm UV radiation range penetrates to a depth greater than either (a) the thickness of a wall having an area of 65 μm^2 +/- 49 μm^2 as disclosed in James or (b) the 65 μm wall thickness that the Examiner asserts is necessary. A person of ordinary skill in the art, therefore, could implement the claimed methods using pulse/power parameters that reach the desired tissue without undue experimentation.

B. Response to § 112, second paragraph Rejection

Claim 1-3, 5-11 and 13-15 were rejected under 35 U.S.C. § 112, second paragraph, on the grounds that "a wavelength of about 240 nm to about 280 nm" is unclear in light of the ranges in claims 5, 6, 13 and 14. Claims 5, 6, 13 and 14 have been canceled without prejudice, and thus the wavelength range in claims 1 and 10 is sufficiently definite to a person of ordinary skill in the art to ascertain the scope and meaning of claims 1-3, 7-11 and 15. Claims 8 and 11 were rejected on the grounds that it was unclear what the features in these claims were intended to imply. These claims have been canceled without prejudice and without conceding the merits of this rejection. Therefore, this rejection should be withdrawn.

C. Response to § 102(b) Rejection: Ivanyuta

Claims 1-3, 5-11 and 13-15 were rejected under 35 U.S.C. § 102(b) as being anticipated by Ivanyuta. In light of the Notice of Appeal filed concurrently with this paper, the applicant will substantively address this rejection in an appeal brief that will be filed in the course of the appeal.

D. Response to § 103(a) Rejection: James, Clarke, Regunathan and Waksman

Claims 1-3, 5-11 and 13-15 were rejected under 35 U.S.C. § 103(a) as being unpatentable over James in combination with Clarke, Regunathan and Waksman. In light of the Notice of Appeal filed concurrently with this paper, the applicant will substantively address this rejection in an appeal brief that will be filed in the course of the appeal.

E. Response to the Double Patenting Rejection of Claims 1-3, 5-11 and 13-15

Claims 1 and 10 were rejected under the doctrine of obviousness-type double patenting over the claims of U.S. Patent Nos. 7,027,869, 6,634,363, 6,411,852, 6,299,633, 6,283,989, 6,283,988, 6,200,333, 6,083,255, 6,273,907, and 5,972,026. Claims 1 and 10 were also rejected under the doctrine of provisional obviousness-type double patenting over the claims of co-pending U.S. Application Nos. 11/608,606, 11/562,925, 11/398,353, 11/408,668, 11/420,442, 11/361,564, 11/117,905, 11/617,512, 11/614,914, 11/534,621, 11/608,606, and 11/361,564.

Claims 1-3, 5-11 and 13-15 were rejected under the doctrine of obviousness-type double patenting over the claims of U.S. Patent Nos. 6,488,673, 7,264,002, and 7,273,055. Claims 1-3, 5-11 and 13-15 were also rejected under the doctrine of provisional obviousness-type double patenting over the claims of co-pending U.S. Application Nos. 11/614,919, 11/612,620, 11/618,533, 11/609,242, 11/425,345, 11/421,444, 09/095,323 and 11/562,910.

The applicants respectfully submit that pending claims 1-3, 5-11 and 13-15 are not obvious in light of the claims of the above patents and applications, and thus applicants respectfully do not concede the merits of these rejections. With respect to the copending applications in the foregoing obviousness-type double patenting rejections, if the present application is in condition for allowance before issuance of the listed copending applications, then the present application should not be subject to an obviousness-type double patenting rejection over those applications. (MPEP § 804.) The present application

antedates all of the copending applications listed in the obviousness-type double patenting rejections, and thus the filing of Terminal Disclaimers regarding the above listed copending applications will be fully addressed upon an indication of allowable subject matter. The applicant respectfully requests a stay of this rejection pending the outcome of the appeal process or an earlier issuance of one of the cited copending applications. Upon an indication of allowable subject matter, the filing of Terminal Disclaimers regarding the above listed co-pending applications will be fully addressed. With respect to the obviousness-type double patenting rejection over the issued patents, enclosed with this response are Terminal Disclaimers regarding U.S. Patent Nos. 5,972,026; 6,083,255; 6,200,333; 6,273,907; 6,283,988; 6,283,989; 6,299,633; 6,634,363; 6,411,852; 6,488,673; 7,027,869; 7,264,002; and 7,273,055. Therefore, the applicants respectfully request withdrawal of the obviousness-type double patenting rejection over the listed patents.

F. Conclusion

The applicant respectfully requests that the foregoing amendments be entered to put the claims in better condition for appeal.

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Respectfully submitted,

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